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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,530	02/21/2002	Sanjeev Redkar	12636-267	8656

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1618

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,530

Applicant(s)

REDKAR ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9, 14-17, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 14-17, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 4/18/05.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-4, 9, 14-17, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Wall et al (USPN 6,288,072 hereafter '072) and Comins et al (USPN 5,162,532 hereafter '532). The claims are drawn to a 9-nitrocamptothecin in crystalline form.

4. The '072 reference discloses camptothecin formulation (abstract), including 9-nitrocamptothecin compounds (col. 5, lin. 45-50, col. 6, lin. 15-20). The camptothecin compounds include solvates, hydrates and polymorphs (col. 4, lin. 25-30). The compounds are placed into pharmaceutical formulations comprising carriers (col. 8, lin. 35-col. 11, lin. 29). The reference however is silent to the particular properties of the claims.

5. The reference is silent to the differential scanning calorimetry readings as well as the X-ray powder diffraction, or the Kappa radiation characteristics. However, since applicant has not disclosed a specific 9-nitrocamptothecin compound, nor defined the specific activity of the

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compound it is the position of the examiner that such limitation do not impart patentability on the instant compound and would be inherent to any 9-nitrocamptothecin compound. Applicant is invited to provide evidence of a patentable distinction between the functions of the instant compound and that of the prior art, since the compound must be defined by its function and not by its properties. Also applicant must provide a specific structure of the instant compound. As a compound camptothecin has multiple positions for additions and functional groups. Applicant has only provided one functional group, which does not clearly define the structure of the instant claims. Therefore, applicant is requested to provide the specific structure and function of the camptothecin compound of the instant claims.

6. As discussed above the '072 patent discloses a 9-nitrocamptothecin compound. The reference is however is silent tot specific solvent used to process the compound, however their use is well known and well within the level of ordinary skill in the art. As seen in the '532 patent that discloses camptothecin analogues such as 9-nitro (col. 6, lin. 64-68) processed using solvents such as tetrahydrafuran and acetonitrile (col. 3, lin. 45-50). A skilled artisan would be motivated to process the compounds of '072 with the solvents of '532 in order to properly process the camptothecin compounds allowing for improved pharmaceutical properties.

7. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious

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difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

8. With these things in mind one of ordinary skill in the art would have been motivated to process the camptothecin analogue of '072 with the solvent of '532 in order to ensure proper processing of the compound. It would have been obvious to, and well with the level of skill in the art to combine these disclosures with an expected result of a cancer-fighting compound with improved delivery properties.

Response to Arguments

9. Applicant's arguments filed 4/18/05 have been fully considered but they are not persuasive. Applicant argues that:

- a. The Wall reference does not teach the 9-nitrocamptothecin compound of the instant claims
- b. Since Wall does not teach the compound there is no motivation to combine Wall with the Comins.

Regarding argument a., it is the position of the Examiner that the compound of Wall discloses a species to the genus of the 9-nitocamptothecin recited in the instant claims. The compounds of Wall are solid and have nitrogen molecules at the 9-position, meeting the limitations of the 9-nitocamptothecin. Applicant has yet to further define the functional groups at the remaining positions. Applicant is reminded that a species obviates a genus absent evidence to the contrary. Applicant is invited to provide evidence and disclosures to the structure of the camptothecin compound of the instant claims. Until such time the claim will remain obviated by the art.

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Regarding argument b., as discussed above the compound of Wall obviates the genus recited in the claims. The reference is however silent to the solvent used in processing the compound. Comins however discloses camptothecin compounds processed with tetrahydrofuran and acetonitrile. The reference established the level of skill in the art regarding the processing of camptothecin compounds with well-known solvents. It would have been obvious to dissolve the compounds of Wall with the solvents of Comins in order to properly dissolve the compound. These disclosures render the claims obviated.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


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